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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,764	03/16/2001	Zoran Ristic	P03965US1	7108

27142 7590 06/09/2004

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/810,764	<b>Applicant(s)</b> RISTIC ET AL.	
	<b>Examiner</b> Ashwin Mehta	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16,18,19,21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,14-16,18,21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the claim for priority on page 1 of the specification is withdrawn, in light of its amendment.
3. The objection to the specification for failing to comply with 37 CFR 1.821-1.825 is withdrawn, in light of the insertion of sequence identifiers in the appropriate locations.
4. The objection to claims 20 and 21 is withdrawn, in light of the cancellation of claim 20.
5. The objection to claim 22 is withdrawn in light of its cancellation.

***Claim Rejections - 35 USC § 112***

6. Claims 1, 3-7, 14-16, and 18 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed July 1, 2003. Applicants traverse the rejection in the paper submitted 29 September 2003. Applicants' arguments were fully considered but not found persuasive for the rejections maintained and discussed below.

Claim 1 was rejected because the recitation, "is expressed primarily under heat shock conditions" made it unclear whether the isolated nucleotide sequence also comprises a heat shock promoter. Applicants argue that one skilled in the art would know what promoters to use to express the nucleotide sequence at times of stress (response, page 10, 3<sup>rd</sup> full paragraph). However, the rejection was questioning if the native nucleotide sequence encoding it is induced under heat shock conditions. Further, the recitation is supposed to be characterizing the protein, not the nucleotide sequence. As it is clear that one skilled in the art may attach any desirable, isolated promoter to any isolated nucleotide coding sequence, it was not clear how the recitation was further characterizing the regulatory protein.

Claim 14 was rejected as indefinite because the last recited method step was inconsistent with the preamble. Applicants argue that the claim amendment alleviates the rejection (response, page 11, 2<sup>nd</sup> full paragraph). However, the amendment only indicates that transgenic plants are regenerated from the transformed plant cells. The last step does not result in an increase in plant tolerance to heat and drought. It is suggested that the recitation, --, wherein expression of said protein in the transgenic plant increases heat and drought tolerance-- be inserted in the last line after "cells".

7. Claims 1, 3-8, 14-16, 18, 21, and 23-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record

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stated in the Office action mailed July 1, 2003. Applicants traverse the rejection in the paper submitted 29 September 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the Examiner merely notes that the specification fails to describe a nucleotide sequence other than SEQ ID NO: 6 and that because "high homology" and "high stringency" are not defined the structural relationship between the claimed nucleotide sequences and SEQ ID NO 6 is not defined. Applicants argue that they are not required to disclose each species encompassed by a claim and that the specification indicates that any nucleotide sequence encoding an EF-Tu polypeptides may be used in accordance to the invention (response, page 13, last full paragraph and page 14, 1<sup>st</sup> full paragraph). However, the claims only indicate the protein encoded by the nucleotide sequence is expressed under heat shock conditions, is localized in chloroplasts, and that the nucleotide sequence can hybridize to SEQ ID NO: 6 under the recited conditions. The claims do not recite any function for the nucleotide sequence or the regulatory protein it encodes. The claim encompasses nucleotide sequences that can have any function, including those that are not described in the specification and not possessed by SEQ ID NO: 6. Applicants argue that the combination of coding function in conjunction with the hybridization conditions and knowledge of those skilled in the art on isolating and identifying claimed polynucleotides make clear that Applicants have described the claimed nucleotide sequences (response, page 14, 3<sup>rd</sup> full paragraph). However, the claims do not recite any function.

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8. Claims 1, 3-8, 14-16, 18, 21, and 23-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed July 1, 2003. Applicants traverse the rejection in the paper submitted 29 September 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the specification indicates that methods for isolating other polynucleotides are known to those of skill in the art will typically be based on screening for other plants with heat and drought tolerance and which express EF-Tu during stress (response, page 16, 1<sup>st</sup> full paragraph). However, methods of isolating a nucleotide sequence are not methods of making it. See Bayer AG v. Housey Pharmaceuticals Inc., 68 USPQ2d 1001 (CA FC 2003), at page 1009 where it states, "We agree with the district court's conclusion that "processes of identification and generation of data are not steps in the manufacture of a final drug product.""

Applicants argue, in response to the issue that the specification does not teach that all EF-Tu proteins increase heat and drought stress in plants, that certain passages on pages 7 and 11 of the specification teach that the EF-Tu can be any of the family of 45kD heat shock proteins including SEQ ID NOs: 1-3, and those substantially equivalent thereto, and that synthesis of chloroplast EF-Tu stabilizes plants during stress (response, paragraph bridging pages 17-18). However, the specification teaches that multiple 45 kD heat shock proteins were synthesized in the chloroplasts of the heat and drought tolerant maize line ZPBL 1304, with the protein encoded by SEQ ID NO: 6 being just one. The

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specification does not show that transgenic plants expressing only SEQ ID NO: 6 have increased drought and heat tolerance.

In response to the issue that claim 7 encompasses non-plant eukaryotic cells, Applicants argue that the specification teaches that Example 5 teaches the expression of EF-Tu in *E. coli* (response, page 18, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs). However, the rejection raised the issue of lack of enablement of non-plant eukaryotic host cells, and the Office action suggested limiting claim 7 to bacterial and plant host cells.

9. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Murayama et al. (Plant Mol. Biol, 1993, Vol. 22, pages 767-774) , for the reasons of record stated in the Office action mailed July 1, 2003. Applicants traverse the rejection in the paper submitted 29 September 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that there is not teaching that the protein is expressed under heat shock conditions, and that the reference does not suggest the role of EF-Tu in conferring heat and drought tolerance (response, page 19, 3<sup>rd</sup> full paragraph). However, the property of being expressed under heat shock conditions is inherent to the protein, absent evidence to the contrary. Further, the discovery of a new role or property of a prior art product does not make that product patentable. That the nucleotide sequence disclosed in the reference can hybridize to instant SEQ ID NO: 6 under conditions equivalent to those recited in claim 1 is a property that is also inherent to the sequence. The structure of the nucleotide sequence disclosed in the reference is not changed by any newly discovered role or property.

***Summary***

10. Claims 1, 3-8, 14-16, 18, 21, and 23-31 remain rejected. Non-elected claims 9-13 and 19 remain withdrawn from consideration.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Contact Information***

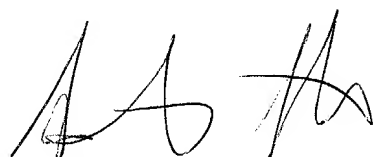
Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307



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for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 7, 2004

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is positioned above the printed name.

Ashwin D. Mehta, Ph.D.  
Primary Examiner  
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